

surgery at any time during the study period was present in 94.5%, 91.2%, and 65.9% of patients, respectively (5.5% of patients had no claims indicating any prior cancer treatment). Mean length of chemotherapy treatment was 806 days, and 571 days for biologic treatment. **CONCLUSIONS:** Patients initiated on regorafenib were largely suffering from metastatic cancer, and had a range of comorbid conditions. Nearly all patients were treated with chemotherapy and/or biologic agents before initiating regorafenib treatment.

PCN178

USE OF BONE-MODIFYING AGENTS FOLLOWING ANDROGEN DEPRIVATION THERAPY FOR MEDICARE NON-METASTATIC PROSTATE CANCER PATIENTS

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OBJECTIVES: Guidelines on the management of cancer treatment-induced bone loss (CTIBL) in men receiving androgen deprivation therapy (ADT) for prostate cancer (PC) recommend bisphosphonate (BP) therapy or other bone-modifying agents (BMAs). There is limited information on the use of BMAs for CTIBL in men with PC. We examined BMA utilization patterns following ADT initiation among elderly men with non-metastatic PC. **METHODS:** Using linked Surveillance, Epidemiology, and End Results (SEER) & Medicare data, we identified men aged 66+ with incident non-metastatic PC diagnosed during 2007-2009, with claims from 2006-2010. Patients received ADT within 6 months after diagnosis and had at least 6 months of Part D enrollment during follow-up. Multivariable logistic regression model was estimated to identify demographic and clinical factors associated with BMA utilization following ADT initiation. **RESULTS:** We identified 7,545 non-metastatic PC patients who received ADT (median age: 74). The sample included patients with stage 2 (80%), 3 or 4 (8%), or unstaged (12%) PC. Overall, 8.6% had any BMA use after ADT initiation and the most common BMAs were oral BP (5.2%), intravenous BP (3.3%), followed by calcitonin (0.5%). A small proportion (1.6%) of the sample had any BMA use prior to ADT initiation. The median time to first BMA use after ADT initiation was 189 days. Factors associated with statistically significant increased likelihood of BMA use were older age, poorly differentiated tumor, and presence of osteoporosis. Compared to stage 2 PC patients, those with stages 3 or 4, and unstaged PC were more likely to receive BMA ($p < 0.01$). Patient race/ethnicity, comorbidity profile, and history of fracture were not statistically significantly associated with BMA receipt. **CONCLUSIONS:** Less than 10% of elderly men diagnosed with non-metastatic PC and initiating ADT received any BMA, suggesting that a significant gap remains in the prevention and treatment of CTIBL in this population.

PCN179

THE DOWNWARD TREND IN ONCOLOGY DRUG PRICING, SPEED TO MARKET AND ACCESS

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OBJECTIVES: Quantify the price, time and volume concessions incurred by manufacturers launching new oncology drug treatments across the EU5 in order to gain market access. **METHODS:** We analyzed launches of innovative oncology products in both the US and EU5 since 2005 ($n=23$). Two cohorts (2005-08; 2009-2013) were defined where we analyzed price, volume and access time. We created an overall opportunity index combining these 3 variables. Prices (MSP – Midas) were made relative to the US price. Time to access: 2 points were measured – time from regulatory approval to price approval by authorities where applicable and time to first reported sales. Volume was assessed as units sold over the period cohort, normalized by the local epidemiology. **RESULTS:** Price, time to access and volume are all worsening for all EU markets compared to the US. The overall combined opportunity index has declined or remained low and flat in France (1.22 – 0.93), Germany (0.80 – 0.75), Italy (0.45 – 0.46), Spain (0.67 – 0.39) and UK (0.54 – 0.57). US = 1. **CONCLUSIONS:** Ongoing EU health care budget management have been modifying the relative commercial attractiveness compared to the US of many products including new oncology compounds in Europe. The EU empirical mindset of trading off price to gain faster access to market with no or minimal concession on the usage is not supported by the data. For a health care perspective, the under usage of oncology products potentially and directly impacting overall survival of the patient compared to the US may potentially lead to a lower survival in EU compared to the US. Epidemiologists may only able to detect this consequence in the coming years.

PCN180

FACTORS ASSOCIATED WITH REPEAT MAMMOGRAPHY SCREENING IN THE MEDICAID POPULATION

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OBJECTIVES: Limited information currently exists regarding use of routine mammography screening among Medicaid enrollees. The current study determined the prevalence of repeat mammography screening and the associated factors in the Medicaid population. **METHODS:** The 2006-2008 Medicaid Analytic Extract (MAX) data for 39 states in the United States were used in this study. The target population consisted of female recipients aged 40-64 years who were continuously enrolled in the Medicaid program during 2006-2008. Recipients with a diagnosis of breast cancer were excluded from the study. Repeat mammography screening was defined as receipt of two successive mammograms during the study period with a gap of 10-14 months. The effect of various recipient- and county-level factors on repeat mammography screening was determined using hierarchical logistic regression. **RESULTS:** Approximately 1.19% of the recipients received repeat mammograms during the study period. The repeat mammography screening rates were higher in older women and those belonging to ethnic minorities than younger women and whites. Number of visits to physician offices and outpatient centers, hormone replacement therapy, and routine cervical cancer screening were positively associated with repeat mammography screening. However, number of emergency

room visits was negatively associated with repeat mammography screening. No association was observed between county level characteristics such as number of primary care physicians, number of mammography screening facilities, and number of federally qualified health care centers per 10,000 women and repeat mammography screening. **CONCLUSIONS:** Mammography screening is underutilized in the Medicaid population. Various factors predicting repeat mammography screening were identified. Program planners should consider these factors when designing educational interventions aimed at increasing routine use of mammography screening among Medicaid enrollees.

PCN181

ONCOLOGY PRICING TRENDS IN THE UNITED STATES AND THE UNITED KINGDOM (2011-2013)

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OBJECTIVES: To understand relative price differential for cancer drugs in the U.S. and the U.K. Develop implications for pricing strategy and patient access for cancer drugs. **METHODS:** Ten branded cancer drugs were selected and their prices for similar dose and packaging were compared in the U.S. and the U.K. Prices were analyzed for the end of 2011 and 2012. Historical exchange rates were used to convert British pounds to US dollars. Relative price discount was calculated for all selected cancer drugs. KOLs and payers were interviewed to understand current and future implications of this price differential. **RESULTS:** The median price discount for selected ten branded cancer drugs in the UK versus the United States was ~50%. The range of discount for 10 branded cancer drugs was 27%-61%. The price discount for oral small molecule drugs was higher than for biologics (55% vs. 45%). Since the U.K. is one of the few remaining free pricing markets in Europe, other European markets are likely to have even higher discounts relative to the prices in the U.S. Due to rising co-insurance of specialty products, U.S. cancer patients bear significantly higher costs than patients in the UK. KOL and payer interviews suggest U.S. pricing trends for cancer drugs are unlikely to be sustained at this level in the future. **CONCLUSIONS:** U.S. cancer drug prices are significantly higher than the prices in the U.K. This price differential is unlikely to be sustained in the future.

PCN182

AN APPRAISAL OF PCODR'S DECISIONS AND INFLUENCE OVER THE LAST 3 YEARS

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OBJECTIVES: The purpose of this study was to understand pCODR's impact on provincial formulary decisions since its establishment in 2010. **METHODS:** 29 pCODR reviews were analysed. The agency publishes its reviews on its website, www.pcodr.ca, including final recommendations for provinces to consider in their respective formularies. pCODR also publishes a "Provincial Funding Summary" of 9 provinces (all except Québec) following each of its final recommendations when available. pCODR's recommendations were indexed with corresponding provincial decisions in order to measure the frequency with and degree to which provinces follow pCODR guidance. **RESULTS:** Out of the 29 final recommendations analysed, pCODR has issued 24 positive funding recommendations, including 20 "conditional on cost-effectiveness being improved." Given the 24 positive recommendations, provinces funded products with similar or more restrictiveness than pCODR's recommendation 21.3% of the time and with less restrictiveness 6.9% of the time; provinces remained under consideration, negotiation, or lacked any status update 71.8% of the time. No province has rejected funding of an oncology product following a positive pCODR recommendation. pCODR issued negative funding recommendations 5 of 29 times. Of these, provinces have almost never funded the product in turn. **CONCLUSIONS:** Provinces have tended to follow pCODR's recommendations or not make a decision. Compared to other provinces, Alberta tends to fund products with fewer restrictions than pCODR recommends, while Ontario demonstrates more restrictiveness. Saskatchewan has followed pCODR most closely. Manitoba, New Brunswick, Newfoundland and Labrador, and Prince Edward Island respond most slowly, in "consideration" or "negotiation" of most pCODR recommendations.

PCN183

EFFECTS OF THE PRIMARY PAYER TYPE AND RACE/ETHNICITY ON PROSTATE CANCER SCREENING PRACTICES DURING PREVENTIVE HEALTH EXAMS IN UNITED STATES AMBULATORY CARE SETTINGS

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OBJECTIVES: There is limited information on the relationship between insurance coverage and prostate cancer (PCa)-screening practices among race/ethnic minorities in ambulatory care settings in the US. The objective of this study was to determine whether the observed race/ethnicity differences in prostate-specific antigen (PSA)-screening for PCa may be explained by differences in insurance coverage. **METHODS:** We analyzed a nationally representative sample of visits to office-based physicians' practices from 2005-2010 using the National Ambulatory Medical Care Survey (NAMCS). The sample consisted of outpatient visits for preventive health exams (PHEs) of men aged 40 years and above, without PCa. The primary insurance payer categories were mutually exclusive and included the following: Medicare, Medicaid, private insurance and other types. Information on the receipt of PSA-screening, demographics, physician specialty and type of office setting were collected. Generalized estimating equations were used to investigate the effect of race and insurance type on PSA-screening. **RESULTS:** Application of the inclusion criteria resulted in 5,829 office-visits for PHEs. Majority (57%) of the sample was aged below 66 years, 10% were African Americans and 9% Hispanics. Over 47% were covered by private insurance, 39% by Medicare and 5% Medicaid. Overall, 16% received PSA-screening during a PHE. Hispanics (prevalence ratio:0.62, 95%CI:0.43-0.90) and Medicaid (prevalence ratio:0.24, 95%CI:0.11-0.55) patients were less likely to receive PSA-screening compared to Whites and patients with private insurance. PHEs

conducted in health maintenance organizations were more likely to have a PSA-screening, compared to physician group settings. General practitioners were more likely to receive PSA-screening compared to other types of specialists. Interactions between race and insurance type were not significant. **CONCLUSIONS:** Hispanics and individuals insured by Medicaid are less likely to receive PSA-screening during an ambulatory care office-visit for a PHE. Efforts to improve access to cancer-screening services are warranted for these groups. It is necessary to consider the differential impact of PCa-screening policies on medically underserved populations.

PCN184

CANCER CARE COSTS TREND IN THE UNITED STATES: FINDINGS FROM THE MEDICAL EXPENDITURE PANEL SURVEY 2008-2011

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OBJECTIVES: To estimate the annual financial burden of cancer care in the United States and to study the effects of cancer on total health care of the country. **METHODS:** Direct medical cancer care costs for the years 2008-2011 were estimated using the household component of the Medical Expenditure Panel Survey (MEPS), a nationally representative survey that includes self-reported health care utilization and expenditures for the US civilian non-institutionalized population. The likelihood of having a cancer diagnosis by age, race and insurance status and other variables were also assessed. **RESULTS:** Aggregate cost of cancer in the US increased from \$183 billion in 2008 to \$236 billion in 2011. While total out-of-pocket (OOP) costs per cancer case decreased from \$1,419.43 in 2008 to \$1,254.77 in 2011, total cost per case increased from \$10,461.66 to \$12,583.69 over 2008 to 2011. The OOP and total medical care expenditures per case in 2008 were \$1,560.54 and \$11,501.69 respectively in 2011 prices using Urban Medical Consumer Price Index. OOP per case declined at an annual rate of 7.3% while the total direct cost increased at an annual rate of about 3%. Whites, females and 45-64 year olds were more likely to have a cancer diagnosis and most cancer care costs were covered by private insurers. Geographical location was not associated with cancer diagnosis although the southern region has the highest concentration. **CONCLUSIONS:** Our study confirms that cancer is a significant cost driver of the US health care system. Due to expected increase in the number of incident cases and survival rate, total cost of cancer is likely to increase rapidly over the next decade. With the implementation of the Affordable Care Act, burden of cancer care costs on taxpayers will increase due to higher insurance coverage and lower OOP cost.

PCN188

AN ONLINE PATIENT-ORIENTED RADIATION RISK ASSESSMENT TOOL TO PROJECT CANCER RISK FOLLOWING EXPOSURE TO LOW-IONIZING RADIATION IN CANADA

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OBJECTIVES: Increasing use of imaging procedures has raised concerns about the risk of cancer due to repeated exposure to low-ionizing radiation. We developed an online radiation risk assessment tool to project the lifetime attributable risk (LAR) of cancer incidence following repeated exposure to imaging procedures. **METHODS:** We developed a risk projection model to assess radiation exposure from imaging procedures, to estimate the lifetime attributable risk (LAR) of cancer incidence and 95% uncertainty limits (UL), according to age, gender, and imaging type. We used the "linear no-threshold" models (extrapolation of risk associated with high-dose ionizing radiation to low-dose exposure). The model has been adjusted using Canadian data to reflect the Canadian population. **RESULTS:** Selected simulation results are presented. The LAR of cancer incidence for a 50 and 70 year old male, exposed to a single coronary angiogram is 11 (95% UL: 6-22) and 6 (3-12) per 10,000 exposed, respectively. As the number of coronary angiograms increased from one to five over time, the cancer risk increased to 54 (27-106) and 26 (14-52) per 10,000, respectively. As age increases the excess lifetime risk of cancer decreases. The excess lifetime risk of cancer is higher for females than for males. The LAR of cancer for a 70 year old male and female, exposed to a computed tomography (CT) for suspected stroke is 4 (2-8) and 5 (3-10) per 10,000, respectively. As the number of CT scans increased from one to five, the total risk of cancer increased to 17 (8-33) and 23 (12-43) per 10,000, respectively. **CONCLUSIONS:** Patients are rarely aware of radiation risk. Physicians often underestimate the magnitude of radiation doses arising from imaging procedures. An online, interactive model might facilitate the decision making process, leading to more informed decisions and improved clinical outcomes.

PCN189

REIMBURSEMENT RECOMMENDATIONS FOR CANCER PRODUCTS WITHOUT STATISTICALLY SIGNIFICANT OVERALL SURVIVAL DATA: A REVIEW OF CANADIAN PCODR DECISIONS

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OBJECTIVES: Overall survival (OS) data for cancer products is an important endpoint to payers. This study sought to examine (1) what proportion of positive reimbursement recommendations by the pan-Canadian Oncology Drug Review (pCODR) occurred despite unavailable statistically significant overall survival data, and (2) the proportion of negative recommendations that noted a lack of overall survival data as a contributing factor. **METHODS:** Recommendations publicly accessible at www.pcodr.ca and reimbursementdecisions.com were reviewed for the period 13 July 2011 - 9 December 2013. **RESULTS:** During this time period, 28 submissions containing 32 oncology-specific indications were deliberated on by the pCODR committee. Of the eight indications that received a negative recommendation, only one had statistically significant overall- and progression-free survival data. A total of 24 indications received positive recommendations. Of these, two were based on single-arm Phase II clinical trials. The remaining 22 positive recommendations were based on

randomized controlled trials (RCTs), with 19 including OS as an endpoint. Seven of these 19 indications had statistically significant OS data based on the most recent data cut included in the manufacturer's submission to pCODR, while the remaining 12 either did not have statistically significant OS data or the OS data were immature (i.e., median OS not yet reached) at the time of submission. More than half of the 12 submissions with non-significant OS trial data allowed cross-over in the trial (n=9) thereby potentially confounding the clinical benefit of the active therapy. Of the 19 positive recommendations which had an RCT design and assessed OS as an endpoint, progression-free survival (PFS) was statistically significant with or without additional clinically or statistically significant secondary endpoints. **CONCLUSIONS:** This study highlights that positive pCODR recommendations may be in the absence of a clear OS benefit, provided strong PFS and/or additional endpoint data exist.

PCN190

INSIGHTS INTO THE PAN-CANADIAN ONCOLOGY DRUG REVIEW RECOMMENDATIONS - THREE YEARS AFTER ITS INCEPTION

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BACKGROUND: In 2010, the permanent national oncology-specific drug review process, pan-Canadian Oncology Drug Review (pCODR), was established to assess the clinical evidence and cost-effectiveness of new cancer drugs and provide recommendations to the provinces (except Quebec) and territories to guide their drug funding decisions. **OBJECTIVES:** This study sought to identify characteristics and decision patterns of the pCODR recommendations. **METHODS:** Twenty-eight recommendations, covering 33 requested populations, publicly accessible at www.pcodr.ca were reviewed since pCODRs operation: 13 July 2011 - 9 December 2013. Additional information was obtained from the www.reimbursementdecisions.com database. **RESULTS:** Of the twenty-four positive recommendations for coverage, three suggested a more limited patient population than the one requested. Four population funding requests received positive recommendations for the requested population without conditions. In seventeen cases, positive recommendations for the requested population were made conditional on improvement of cost-effectiveness ratios. Nine negative recommendations were made due to: a) limitations in evidence from phase two trials; b) modest progression-free survival, lack of statistically significant overall survival, lack of quality of life data and poor cost-effectiveness, and/or; c) unclear clinical benefit and an unacceptable cost-effectiveness model. Many economic reviews by pCODR included re-analyses of the cost-effectiveness ratios which in some cases had substantial impact on cost-effectiveness. The most common changes from the submitted analyses where limiting product benefit post-progression, time horizon reductions, or changes to post-progression mortality risk. **CONCLUSIONS:** Most submissions resulted in a positive funding recommendation. The positive conditional pCODR recommendations support a continued provincial product listing agreement structure that includes rebates to lower cost-effectiveness. The economic re-analyses of the post-progression survival benefit indicates a need for manufacturers to provide comprehensive consideration of uncertainty surrounding such benefits in the submitted cost-effectiveness analysis.

PCN191

LESSONS FOR ADAPTIVE LICENSING: ANALYSIS OF CONDITIONALLY APPROVED EMA COMPOUNDS, THEIR REIMBURSEMENT STATUS AND REGULATORY/REIMBURSEMENT DATA REQUIREMENTS

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OBJECTIVES: Understand how conditionally approved (CA) compounds in the EMA have performed in reimbursement assessment. Findings will inform current adaptive licensing initiatives. **METHODS:** EMA EPAR reports were analysed to identify CA compounds from 2006-2013. HTA reports from national reimbursement authorities of the UK (NICE, SMC), France (HAS), Germany (G-BA) and Italy (AIFA) were also analysed to understand reimbursement status of these products. **RESULTS:** 20 CA compounds were identified: 11 with current CA status, 7 fully approved and 2 withdrawn. Approval was based upon strength of clinical data from PII/PIII studies. In France, 86% of CA indications were reimbursed, most with an ASMR V. In Italy, 62% of CA indications were reimbursed. Risk sharing agreements (RSA) were used in at least 38% of approvals. In Germany, approximately 50% of CA products licensed after AMNOG were reimbursed. In the UK, only 6 CA products received a positive NICE recommendation, 5 under RSAs to fulfil the cost-effectiveness criteria. CA is granted on limited clinical evidence. Countries using a therapeutic-benefit assessment (e.g. France) reimbursed more CA compounds than cost-effectiveness (CE) driven countries (e.g. UK). RSA is a key tool to win reimbursement in cost-effectiveness countries where high ICER thresholds impeded reimbursement (Bosutinib) or insufficient clinical data (Paxantrone). Positive reimbursement decisions were driven by robust clinical data in orphan or small indications with limited therapies. Strategies employed by companies to overcome payer concerns include: 1) Initial restriction of compound approval to small high unmet need subpopulations; 2) Performance or financial risk sharing arrangements; 3) On-going evidence development plans. **CONCLUSIONS:** Reimbursement outcomes for CA compounds are variable across the EU. This is due to either clinical or economic uncertainties from evidence produced. To deal with these uncertainties, agreed mechanisms for continual evidence development and RSA implementations should be incorporated into on-going adaptive licensing initiatives.

PCN192

CORRELATION OF HTA DECISION OUTCOMES IN FRANCE AND GERMANY

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OBJECTIVES: The objective of this study is to compare the HTA decisions of oncology products in France and Germany and provide insight into the most important asset value attributes that characterise a positive appraisal in these markets. **METHODS:** We analysed the G-BA and the HAS assessments of 11 oncology products published